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EXAMINER	
JEAN-LOUIS, SAMIRA JM	
ART UNIT	PAPER NUMBER
1627	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,674	BROGMANN ET AL.	
	Examiner	Art Unit	
	SAMIRA JEAN-LOUIS	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *45-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/13/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continuation Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/13/09 has been entered.

Response to Arguments

This Office Action is in response to the amendment submitted on 10/13/09. Claims 45-58 are currently pending in the application, with claims 1-44 having being cancelled. Accordingly, claims 45-58 are being examined on the merits herein.

Receipt of the aforementioned amended claims and IDS is acknowledged and has been entered. The Examiner further acknowledges the English Translations of Priority Documents 10215131.8 and 10215067.2 which have also been entered into record.

Applicants traversal of the provisional ODP rejection of claims 45 and 47-58 over claims 1-3, 5, 7-8, 11-17, 43-46, and 48-49 of copending application 10/510,673 is acknowledged, but since applicant did not put forth any arguments against this rejection, the ODP is maintained for reasons of record as stated in the previous office

action and restated below for applicant's convenience. Moreover, given that the Terminal Disclaimer filed by applicant on 10/13/09 was disapproved, the ODP rejection is maintained.

Applicant's argument with respect to the of claims 45-58 under 35 U.S.C. 112, first paragraph for failing to comply with the written description requirement has been fully considered. Given that applicant has amended the claims, such rejection is now moot. Consequently, the rejection of claims 45-58 under 35 U.S.C. 112, first paragraph is hereby withdrawn.

Applicant's contention that neither Kaiko nor Pachter addresses the incorporation of naloxone into an oxycodone dosage form in order to improve the patient's bowel function, let alone the 2:1 oxycodone:naloxone weight ratio in a controlled release matrix as presently claimed has been fully considered but is not found persuasive. Specifically, the Examiner contends that applicant's arguments do not commensurate in scope with the claims. While applicant is arguing the preparation containing oxycodone and naloxone for improvement of a patient's bowel function, the Examiner respectfully reminds applicant that the claims are directed to a pharmaceutical composition comprising oxycodone and naloxone in a ratio of 2:1 and wherein oxycodone is present in an amount of about 10-150 mg and wherein naloxone is an amount of about 1 to 50 mg. Because the claims are directed to a pharmaceutical composition, then a prior art which anticipates or renders obvious the aforementioned drugs in the aforementioned

ratios and ranges will necessarily meet the limitation of the claim regardless of the effect such composition may have on a patient's bowel function.

Kaiko et al. teach an oral dosage form comprising a combination of an orally analgesically effective amount of an opioid agonist and an orally active opioid antagonist, the opioid being included in a ratio to the opioid agonist to provide a combination product which is analgesically effective. Additionally, Kaiko et al. teach that the dosage forms of the invention cam be provided as a sustained release of the opioid agonist and all of the doses of opioid antagonist via the incorporation of a sustained release carrier into a matrix containing the opioid agonist and antagonist; or via a sustained release coating of a matrix containing the opioid agonist and antagonist in ethylcellulose or aqueous dispersion of ethylcellulose sold commercially as Surelease. As the opioid antagonist, Kaiko et al. teach the use of naloxone, where the amount of naloxone included in the dosage form being large enough to provide an equiantagonistic effect as if naltrexone (i.e. another opioid antagonist) were included in the combination. As for the opioid analgesics (i.e. agonists) that are useful in the invention, Kaiko et al. teach the use of several agonists, mixed agonist-antagonists, with oxycodone or pharmaceutically acceptable salts or esters thereof being among the preferred ones that can be administered at an equianalgesic dose of 13.5 mg or a dosages of about 2.5 mg to about 800 mg. Additionally, Kaiko et al. teach that in the prior art oxycodone-naloxone compositions are known to have a ratio of 2.5-5:1 parts by weight and wherein the combination of opioid agonist and opioid antagonist can be

employed in admixtures with convention excipients, including carbohydrates or diluents such as lactose, magnesium stearate, and cornstarch.

Kaiko et al. do not teach a pharmaceutical preparation containing oxycodone-naloxone with the specific weight ratio of 2:1 or a preparation in the form of specific pharmaceutically acceptable and equally active free base salts.

Pachter et al. teach orally effective analgesic composition which does not provide euphoria or physical dependence comprising an oral inactive dose of naloxone and an oral active strong analgetic in oral dosage form and containing for each analgetic dose of the analgetic agent an amount of naloxone sufficient to negate the euphoretic and dependence producing action of the composition. Pachter et al. also teach that naloxone is a potent opioid antagonist that can be used in a dose of 0.1-2.5 mg (see col. 2, lines 40-44 and lines 48). Pachter further teaches that potential analgetics that can be used with naloxone include oxycodone that can be provided in a ratio 2-20 parts to 1 (i.e. 2-20 parts oxycodone to 1 part naloxone) to produce an orally effective analgetic composition which does not produce euphoria or physical dependence (instant claim 45; see col. 5, lines 50-54 and 64). Furthermore, Pachter teaches that the naloxone and the analgetic agents used can include all of the pharmaceutically acceptable nontoxic salts including the hydrochlorides, sulfates, bisulfates, tartrates, nitrates, citrates, bitartrates, phosphates, malates, maleates, hydrobromides, hydroiodides, fumarates, succinates and the like. As a result, the Examiner contends

that one of ordinary skill in the art would have found it obvious to administer the oxycodone-naloxone dosage or particular salts thereof in the formulation of Kaiko et al. in a ratio of 2:1 given that Pachter et al. teach that such ratio provides an effective analgetic composition that negates the euphoria and physical dependence of the composition. Thus, one of ordinary skill would have been motivated to try such ratio and administer the oxycodone-naloxone or salts thereof in the aforementioned ratio with the reasonable expectation of providing an oral composition that is effective in its analgesic effects but also a composition that negates the euphoric and physical dependence associated with such composition.

While applicant argues that Kaiko does not teach any specific ratios of oxycodone to naloxone, the Examiner reiterates the fact that the rejection was made obvious in view of Pachter who teaches the use of 2-20 parts oxycodone to 1 part naloxone in order to produce an orally effective analgetic composition which does not produce euphoria or physical dependence. As a result, the Examiner maintains that one of ordinary skill in the art would have found it obvious administer oxycodone to naloxone in a ratio of 2:1 given the disclosure of Pachter.

While Applicant argues that Kaiko teaches naloxone in a ratio of 1.85 to 14.8:1, the Examiner contends that one of ordinary skill in the art would have found it obvious to try the ratio of oxcydocone:naloxone of 2-20 parts to 1 part since Pachter teaches the use of 2-20 parts oxycodone to 1 part naloxone in order to produce an orally effective analgetic composition which does not produce euphoria or physical dependence. As for

applicant's arguments that Kaiko teaches formulations for oral abuse while Pachter teaches parenteral abuse of opioids, the Examiner contends that one skilled in the art would have found it obvious to try the oral weight ratio disclosed by Pachter since drug abuse occurs via both parenteral and oral route. Consequently, the Examiner asserts that one skilled in the art for the purpose of averting drug addiction in general would have found it obvious to try the weight ratios of oxycodone to naloxone (i.e. 2:1 ratio) with the reasonable expectation that such ratio would indeed be effective in preventing oral addiction. Moreover, Kaiko teaches that the ratio of antagonists to agonists can be readily determined without undue experimentation by one skilled in the art who desires to utilize a different opioid antagonist other than naltrexone (see pg. 14, lines 5-18).

Regarding applicant's arguments that Pachter teaches 200-400 times the dosage of parenteral naloxone which would result in a ratio of oxycodone to naloxone of 2-20:200-400, such arguments are not found persuasive as the Examiner maintains that the above mentioned citation was solely directed to what would be required if an oral dose is desired based on the use of a parental dose of 1.5 mg to 2.5 mg. This in no way negates Pachter's explicit teachings and preferred embodiment which teaches that one part of naloxone can be combined with 2 to 20 parts of oxycodone. As a result, the Examiner maintains that one of ordinary skill in the art would have indeed found it obvious to administer oxycodone:naloxone in a 2:1 ratio as such ratio is taught by Pachter if the desire is to avert drug addiction.

Finally, applicant provided various supporting documents delineating that a weight ratio of 2:1 exhibits improved bowel function and analgesic properties, the

examiner however contends that the combined references of Kaiko in view of Pachter would necessarily possess such properties since Pachter does teach the same weight ratio of 2:1 of oxycodone to naloxone. Because the claims are directed to pharmaceutical composition and not to a method of treatment and thus any properties purported by Applicant is considered to be inherent to such composition. In view of the fact that Kaiko and Pachter render obvious applicant's invention, the Examiner maintains that the modified composition of Kaiko would necessarily possess improved bowel function and analgesic properties and that such properties are in fact expected and obvious.

For the foregoing reasons, the rejection of claims 45-58 under 35 U.S.C. 112, first paragraph is withdrawn. However, the ODP and 103(a) rejection remain proper. In view of applicant's amendment, the following modified ODP and 103 (a) Non-Final rejections are being made.

Provisional Non-Statutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated

by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 45 and 47-58 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5, 7-8, 12-17, 43-46, and 48-49 of copending Application No. 10/510,673 (hereinafter Brogmann US Patent Application No. '673). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a pharmaceutical formulation comprising a combination of oxycodone and/or its pharmaceutically acceptable salts, and naloxone and/or its pharmaceutically acceptable salts, the combination in a controlled release matrix containing ethylcellulose

and at least one fatty alcohol and providing for a sustained release formulation. The claimed invention and co-pending application Brogmann '673 are rendered obvious over another as the claimed invention teaches a subgenus of active agents which include oxycodone and naloxone released from a controlled release matrix whereas Brogmann '674 teaches a broad genus of pharmaceutically active agents that are released from a non-swellable diffusion matrix. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No. 10/510,673.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 45-46, 49-51, and 57 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27, 39-47, and 50-52 of copending Application No. 11/885,288 (hereinafter Leyendecker US Patent Application No. '288). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a pharmaceutical formulation comprising a combination of oxycodone and/or its pharmaceutically acceptable salts, and naloxone and/or its pharmaceutically acceptable salts, the combination in a controlled release matrix containing ethylcellulose and at least one fatty alcohol and providing for a sustained release formulation. The claimed invention and co-pending application Leyendecker '288 are rendered obvious

over another as the claimed invention is silent on the pharmacokinetic profile of the composition whereas Leyendecker '288 teaches a composition with a Tmax for oxycodone of about 1 to about 17 hours. While the instant invention is silent on the pharmacokinetic profile of oxycodone, the Examiner maintains that the instant invention would possess the same pharmacokinetic profile as Leyendecker as both the instant and co-pending applications contain the same exact ingredients. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No. 11/885,288.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 45-58 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Kaiko et al. (WO 99/32119, previously cited) in view of Pachter et al. (U.S. 3,773,955, previously cited).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Kaiko et al. teach an oral dosage form comprising a combination of an orally analgesically effective amount of an opioid agonist and an orally active opioid antagonist, the opioid being included in a ratio to the opioid agonist to provide a combination product which is analgesically effective when the combined oral dosage is administered but is aversive in physically dependent subject (instant claim 57; see abstract, pg. 6, lines 28-30, pg. 7, lines 6-8, and pg. 8, lines 5-10). Additionally, Kaiko et al. teach that the dosage forms of the invention cam be provided as a sustained release of the opioid agonist and all of the doses of opioid antagonist via the incorporation of a sustained release carrier into a matrix containing the opioid agonist and antagonist; or via a sustained release coating of a matrix containing the opioid agonist and antagonist (instant claim 45; see pg. 10, lines 6-15 and pg. 23, lines 6-10). As the opioid antagonist, Kaiko et al. teach the use of naloxone, where the amount of naloxone included in the dosage form being large enough to provide an equiantagonistic effect as

if naltrexone (i.e. another opioid antagonist) were included in the combination (instant claim 45; see pg. 14, lines 15-18). Moreover, Kaiko et al. teach that small doses of 0.4-0.8 mg and up to 24 mg of naloxone in man have been found effective to reverse the effects of opioid agonists (instant claim 45; see pg. 13, lines 21-25). As for the opioid analgesics (i.e. agonists) that are useful in the invention, Kaiko et al. teach the use of several agonists, mixed agonist-antagonists, with oxycodone or pharmaceutically acceptable salts or esters thereof being among the preferred ones that can be administered at an equianalgesic dose of 13.5 mg or a dosages of about 2.5 mg to about 800 mg (instant claims 45-46; see pg. 11, lines 17-20; pg. 15, line 32, pg. 16, lines 11, 15-16 and 23; and pg. 23, lines 17-19). Additionally, Kaiko et al. teach that in the prior art oxycodone-naloxone compositions are known to have a ratio of 2.5-5:1 parts by weight (instant claim 45; see pg. 5, lines 20-22). Moreover, the combination of opioid agonist and opioid antagonist can be employed in admixtures with convention excipients, including carbohydrates or diluents such as lactose (i.e. filler, instant claim 52), magnesium stearate (i.e. lubricant; instant claims 53-54), cornstarch (i.e. flowing agent; instant claim 56; see pg. 19, lines 34-35, pg. 20, lines 5-11, and 19-21; pg. 33, lines 30-32). In the case of oral compositions, the dosage can be provided as tablets, capsules, caplets and gelcaps (instant claim 58; see pg. 9, lines 30-33; pg. 20, lines 14-16, pg. 23, lines 6-10). Suitable sustained release formulations and coatings which may be used include the use of alkylcellulose polymers which provide hydrophobic materials including ethylcellulose or aqueous dispersion of ethylcellulose sold commercially as Surelease (instant claims 45 and 49; see pg. 25, lines 8-10 and 22). Other matrix

formulations include the use of a controlled release matrix that releases the opioid in a pH-dependent or independent manner and includes the use of hydrophobic materials such as fatty acids and fatty alcohols including stearic acid and stearyl alcohol (instant claims 49-51 and 55; see pg. 30, lines 31-35; pg. 31, lines 8-16; pg. 32, lines 10-13 and lines 25-28; and pg. 33, lines 25-27).

Kaiko et al. do not teach a pharmaceutical preparation containing oxycodone-naloxone with the specific weight ratio of 2:1 or a preparation in the form of specific pharmaceutically acceptable and equally active free base salts.

Pachter et al. teach orally effective, analgesic composition which does not provide euphoria or physical dependence comprising an oral inactive dose of naloxone and an oral active strong analgetic in oral dosage form and containing for each analgetic dose of the analgetic agent an amount of naloxone sufficient to negate the euphoretic and dependence producing action of the composition (see abstract, and col. 1). Pachter et al. also teach that naloxone is a potent opioid antagonist that can be parenterally used in a dose of 0.1-2.5 mg (see col. 2, lines 40-44 and lines 48). Pachter further teaches that potential analgetics that can be used with naloxone include oxycodone that can be provided in a ratio 2-20 parts to 1 (i.e. 2-20 parts oxycodone to 1 part naloxone) part naloxone to produce an orally effective analgetic composition which does not produce euphoria or physical dependence (instant claim 45; see col. 5, lines 50-54 and 64). Furthermore, Pachter teaches that the naloxone and the analgetic

agents used can include all of the pharmaceutically acceptable nontoxic salts including the hydrochlorides, sulfates, bisulfates, tartrates, nitrates, citrates, bitartrates, phosphates, malates, maleates, hydrobromides, hydroiodides, fumarates, succinates and the like (instant claims 47-48; see col. 4, lines 14-22).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to administer the oxycodone-naloxone dosage or particular salts thereof in the formulation of Kaiko et al. in a ratio of 2:1 given that Pachter et al. teach that such ratio provides an effective analgetic composition that negates the euphoria and physical dependence of the composition. Given that Kaiko et al. teach oral dosage sustained release formulation comprising a combination of an orally analgesic effective amount of an opioid agonist and an orally active opioid antagonist provided in a controlled release matrix, and Pachter et al. who teach that an analgesic composition of oxycodone to naloxone or salts thereof in a 2:1 ratio is effective in negating euphoria and physical dependence, one of ordinary skill would have been motivated to try such ratio and administer the oxycodone-naloxone or salts thereof in the aforementioned ratio with the reasonable expectation of providing an oral composition that is effective in its analgesic effects but also a composition that negates the euphoric and physical dependence associated with such composition.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L. /

Examiner, Art Unit 1627

12/20/2009

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1627